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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,198	09/30/2003	Lewis George Gradon	1171/39402A/98A-CONT	6059

279 7590 08/25/2005

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CHICAGO, IL 60603

EXAMINER
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MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/675,198

Applicant(s)

GRADON ET AL.

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 08 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/881,394.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection. The Applicant has added new limitations to the claims. The new limitation changes the scope of the claim requiring new consideration and an updated search requiring a new grounds of rejection.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

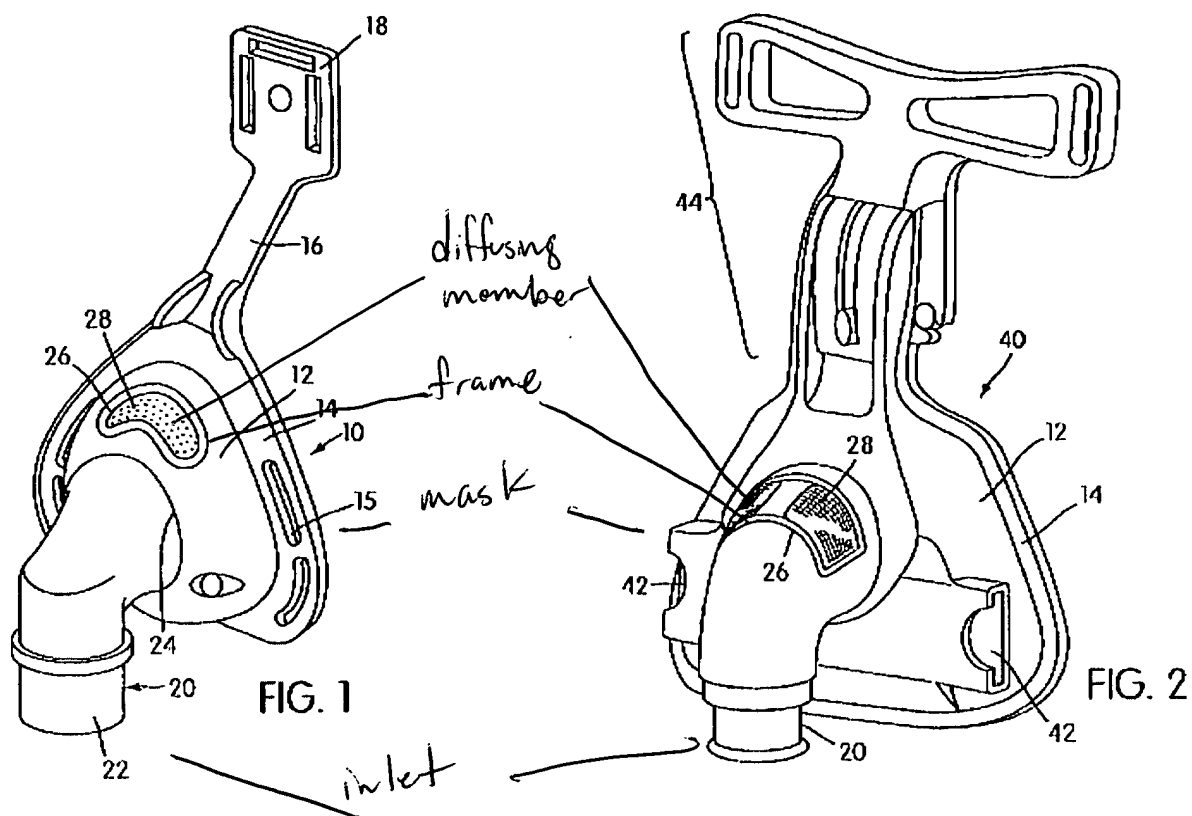
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

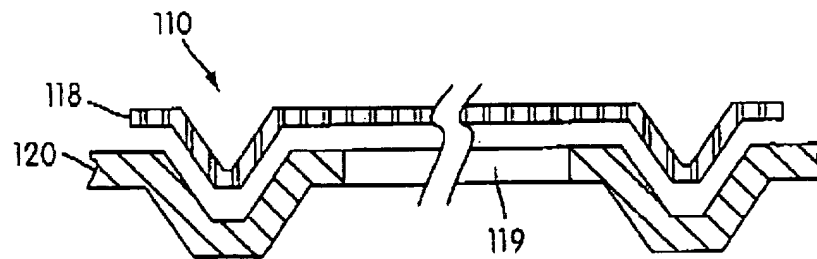
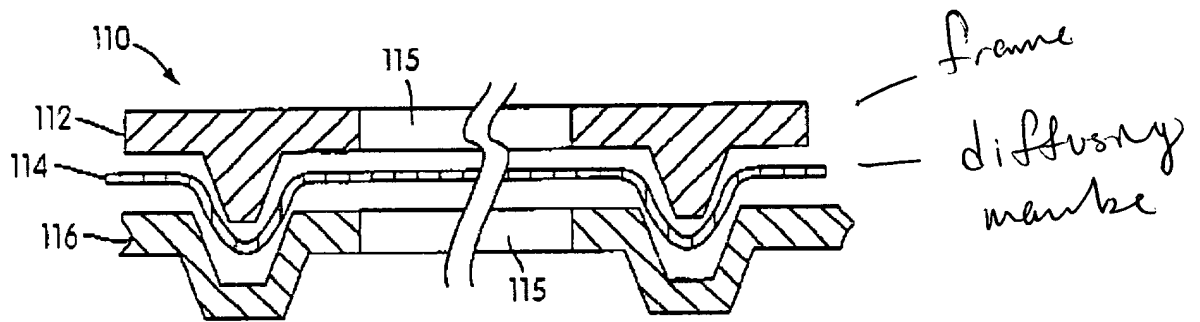
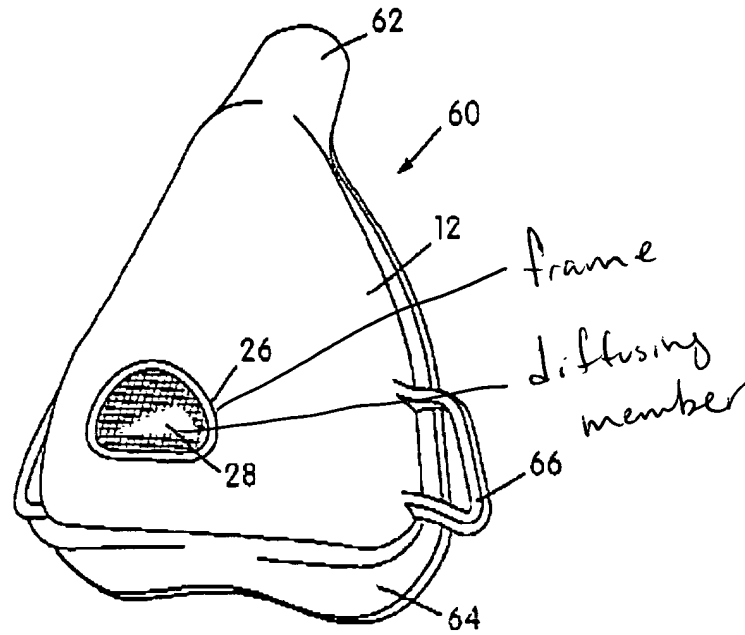
3. Claims 1, 2, and 10-14 are rejected under 35 U.S.C. 102(a) & (e) as being anticipated by Drew et al. 6581594.

4. Drew teaches et al. teaches a device for delivering a supply of gases to a user comprising: a patient interface including a body portion, in use in fluid communication with the supply of gases and supplying the gases to the user, the body portion having at least one outlet vent and at least one aperture to allow passing of gases to the atmosphere; a frame member mountable over the at least one aperture, and a diffusing

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member, the diffusing member being juxtaposed between the frame member and the at least one aperture; wherein the diffusing member is removable and in use diffuses and audibly muffles a substantial portion of the expired gases of the user; and wherein the patient interface comprises a nasal mask having a hard body portion, an inlet to the body portion receiving the supply of gases, sealing means engaged with the body portion, and adapted to seal against the facial contours of the user, and means of securement to the user providing a compressive force on the sealing means mask seal to ensure the supply of gases is delivered to a user without significant leakage, the vent comprising at least one aperture in the body portion.

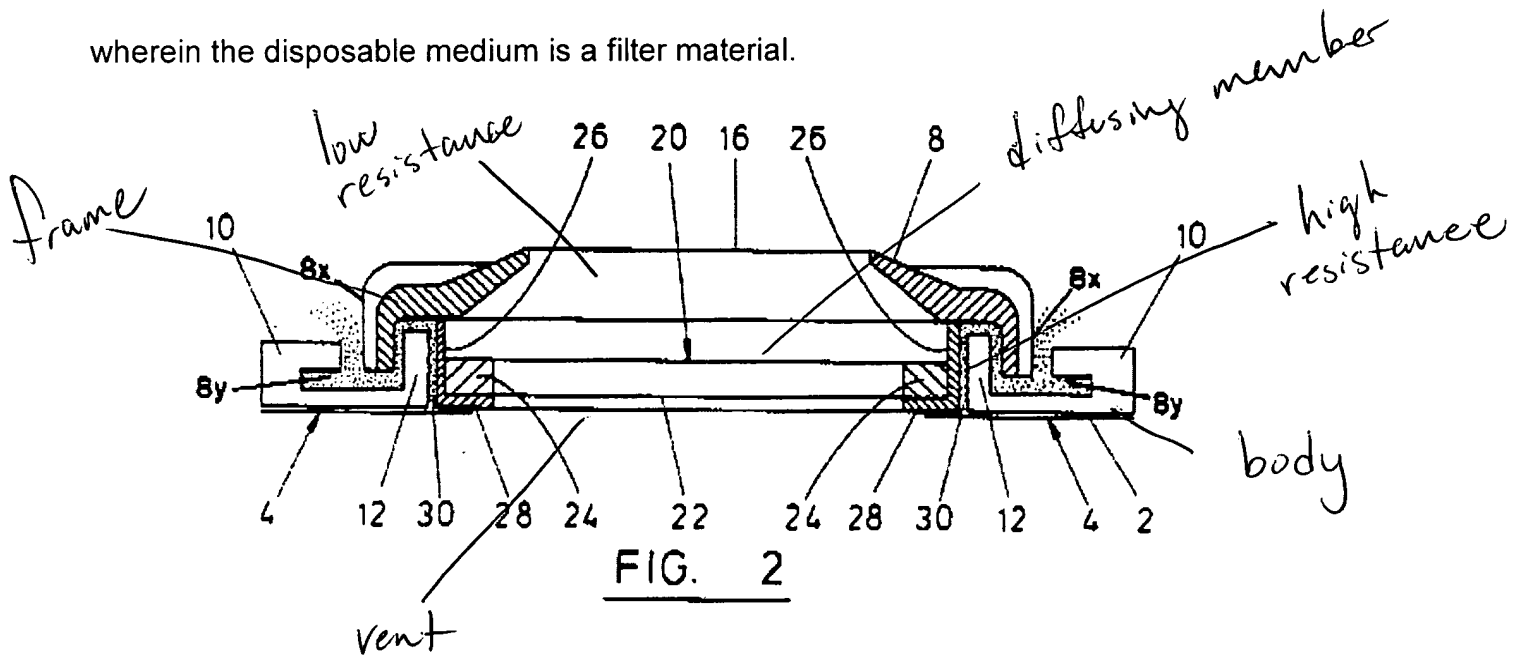




5. Claims 1-9 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith 5848590.

6. Smith teaches in a device for delivering a supply of gases to a user comprising: a patient interface including a body portion, in use in fluid communication with the supply of gases (from atmosphere) and supplying the gases to the user, the body portion having at least one outlet vent and at least one aperture to allow passing of gases to the atmosphere; a frame member mountable over the at least one aperture, and a diffusing member, the diffusing member being juxtaposed between the frame member and the at least one aperture; wherein the diffusing member is removable and in use diffuses and audibly muffles a substantial portion of the expired gases of the user; wherein the frame member and the body portion create a low resistance outlet in parallel with a high resistance outlet, where the low resistance outlet allows the gases to exit to the atmosphere through the diffusing member and the high resistance outlet allow gases to exit directly to the atmosphere; where during normal use the majority of the expired gases passing from the at least one outlet vent and out through the low resistance outlet, whereby if the majority of the expired gases are substantially prevented from passing through the low resistance outlet, the majority of the expiratory gases passing out the high resistance outlet (col. 5, lines 12-20); wherein the high resistance outlet comprises apertures formed into the frame member or in the intersection between the frame member and the body portion; wherein the high resistance outlet is being adapted such that in use the low resistance outlet is blocked or has significant increase in resistance, the high resistance outlet vent a sufficient flow

gas of gases so as to prevent rebreathing of carbon dioxide by the user; wherein the diffusing member is a disposable medium and the low resistance outlet comprising the flow of the expired gases through the disposable medium; wherein the disposable medium reduces the external audible noise level and diffuses the flow pattern that would otherwise occur from the gases flowing through the at least one outlet vent; wherein the disposable medium is a filter material.



### Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not



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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Remarks***

In claim 13 the “said at least one vent” is not positively claimed. If the Applicant desires that the “at least one vent” be a positive claim limitation, the Examiner suggests rewording the claim.

In claim 15 the phrase “in use a low resistance outlet is formed by the flow of expired gases through said disposable medium” is a functional limitation. If the Applicant desires that the “low resistance outlet” be a positive claim limitation, the Examiner suggests rewording the claim.

### ***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon. - Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4498. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM



**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

*8/22/05*